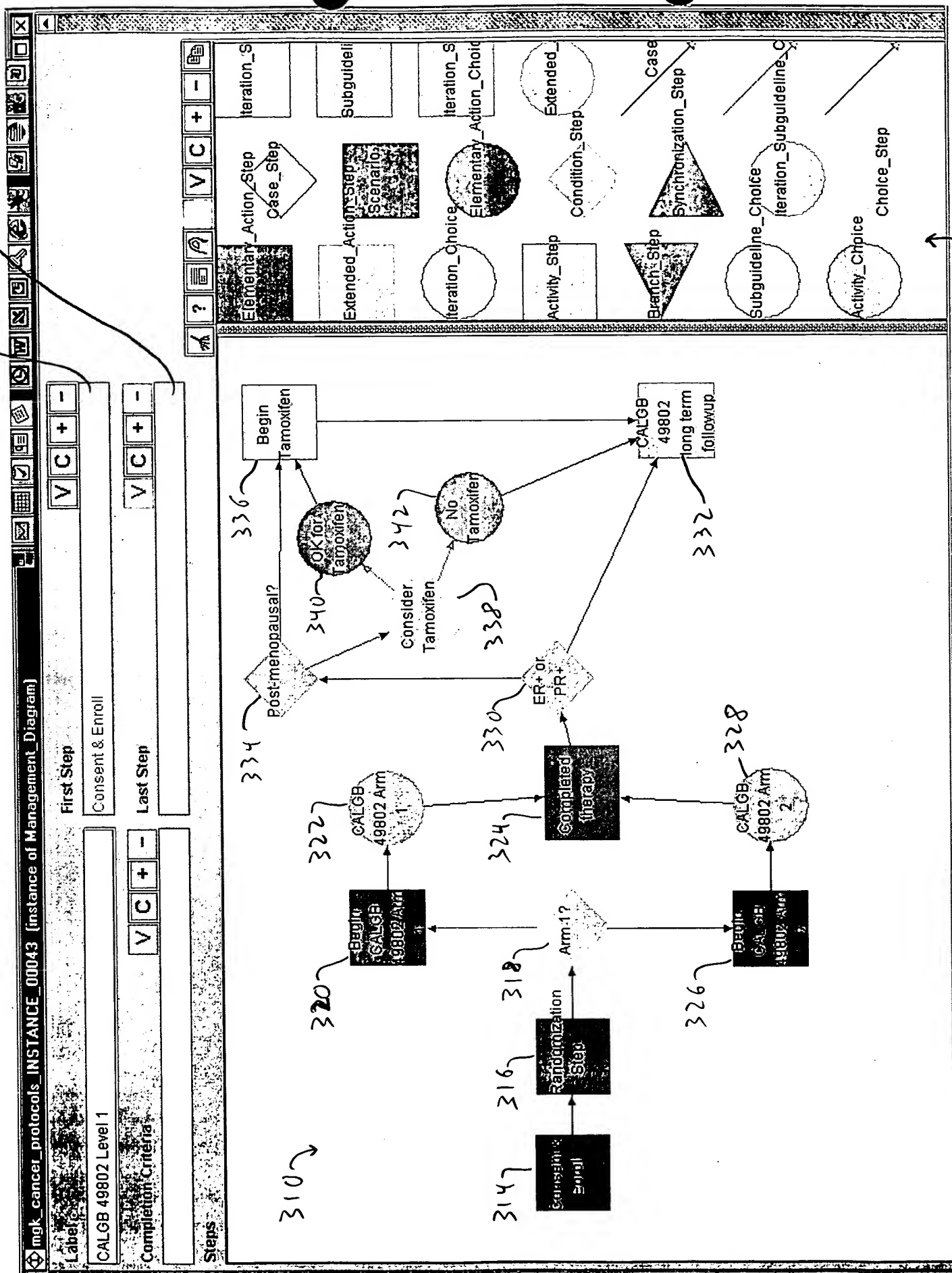


Fig. 1

cancer_protocols_INSTANCE_00039 (Instance of Cancer_Clinical_Protocol)			
Label	Version		
CALGB 49802	mgk 25Jan00		
Title	Authors		
Phase III Study of Adriamycin/Taxotere vs Adriamycin/Cytosan for the Adjuvant Treatment of Node Positive or High Risk Node Negative Breast Cancer	M. G. Public		
Clinical Algorithm	Reference		
CALGB 49802 Level 1	MUSC PRN web page		
Context Reference	Entry Criteria (1 values)		
	<div> <div>Protocol Name</div> <div>CALGB 49802</div> <div>Clinical State Name</div> <div></div> <div>Exclusion List</div> <div> <div>Tumor of any size with direct extension to chest wall or skin (T4)</div> <div>Patient is pregnant or nursing</div> </div> <div> <div>≥ 12</div> </div> </div>		
	<div> <div>Inclusion List</div> <div> <div>Historically or cytologically confirmed invasive breast cancer</div> <div>1-3 histologically involved axillary lymph nodes</div> <div>No evidence of metastatic disease (M0)</div> <div>Absolute neutrophil count at least 1,500/mm3</div> <div>Platelet count at least 100,000/mm3</div> <div>Left ventricular ejection fraction at rest at least 45% by MUGA</div> <div>Bilirubin no greater than 1.2 times upper limit of normal (ULN)</div> <div>Age 18 - 70</div> <div>Effective contraception required of fertile women</div> <div>No prior chemotherapy</div> <div>No prior radiotherapy</div> <div>No concurrent estrogen therapy</div> </div> <div> <div>≥ 10</div> </div> </div>		

Fig. 2



3513

004650*30010300

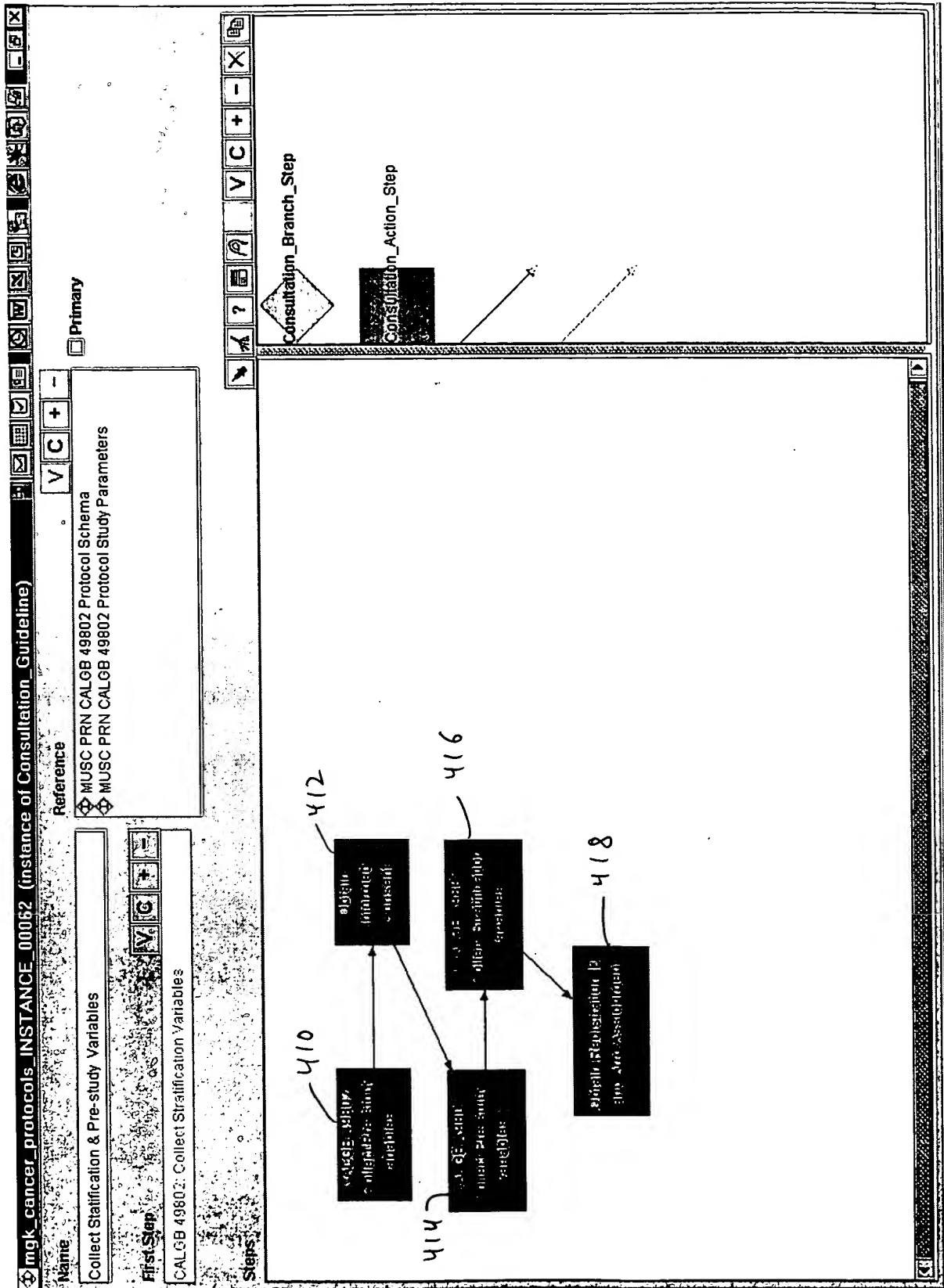


Fig. 4

007550*9201250

mgk_cancer_protocols_INSTANCE_00063 (instance of Consul	
Label	mgk_cancer_protocols_INSTANCE_00063 (instance of Consul
CALGB 49802: Collect Stratification Variable	
Followed by	<div><div>+</div><div>-</div><div>+</div><div>-</div></div> <div>Evaluate lymph node status Evaluate menopausal status Evaluate estrogen receptor status Evaluate progesterone receptor status</div>
Rule In	<div><div>+</div><div>-</div><div>+</div><div>-</div></div> <div>References</div>
Rule Out	<div><div>+</div><div>-</div><div>+</div><div>-</div></div> <div></div>

Fig. 5

007550 950604500

612

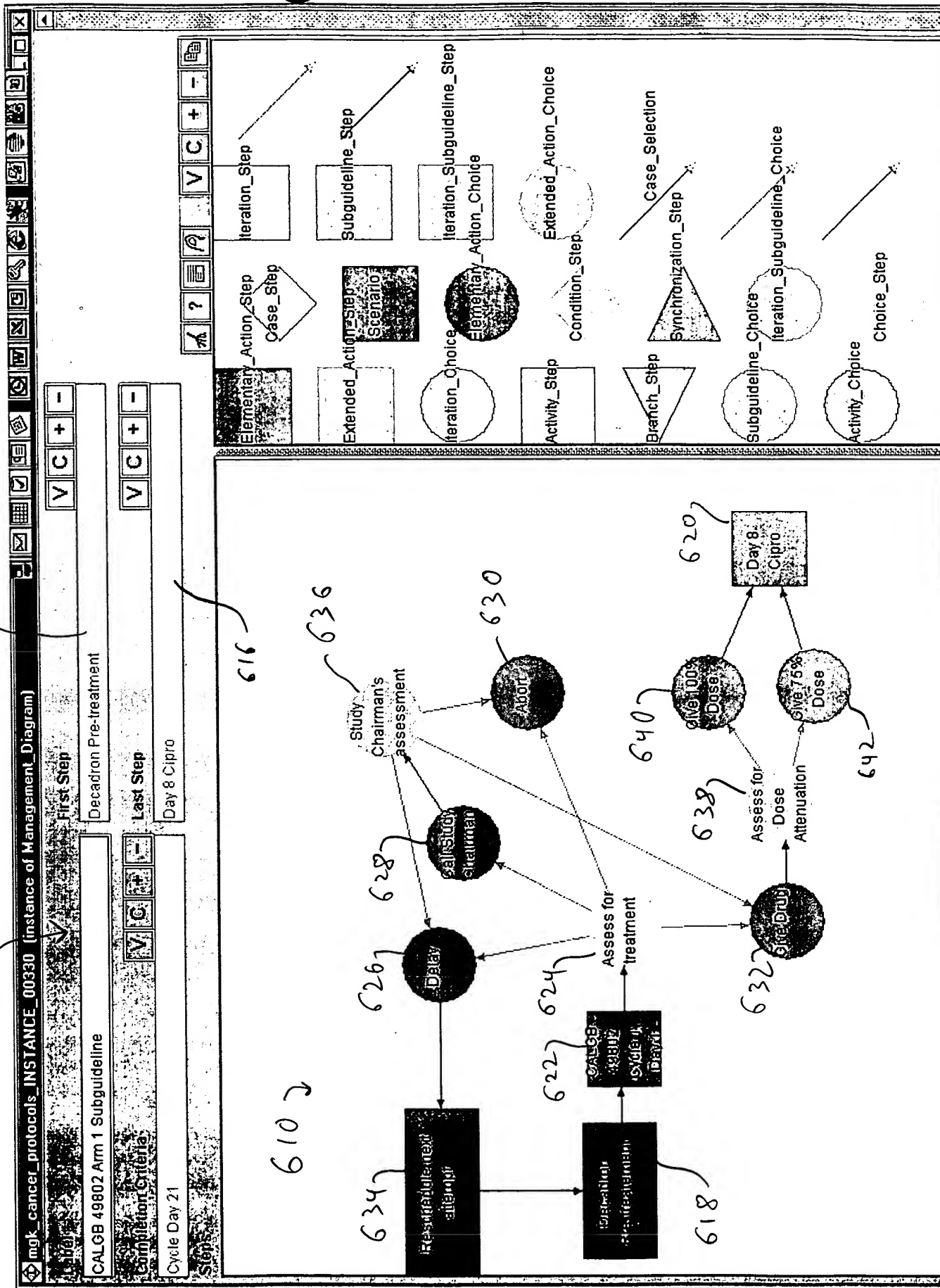


Fig. 6

724

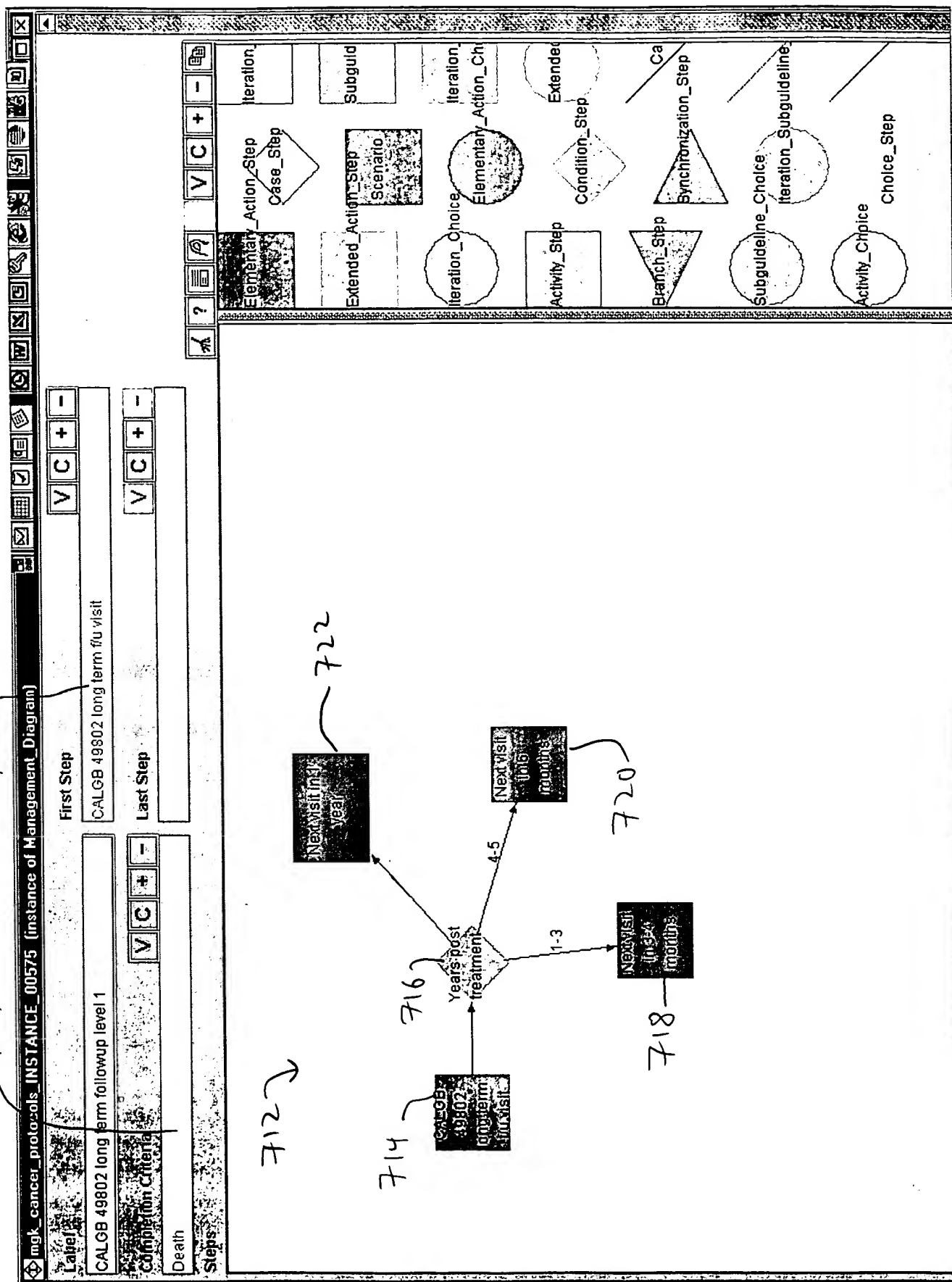


Fig. 7

001550" 95619560

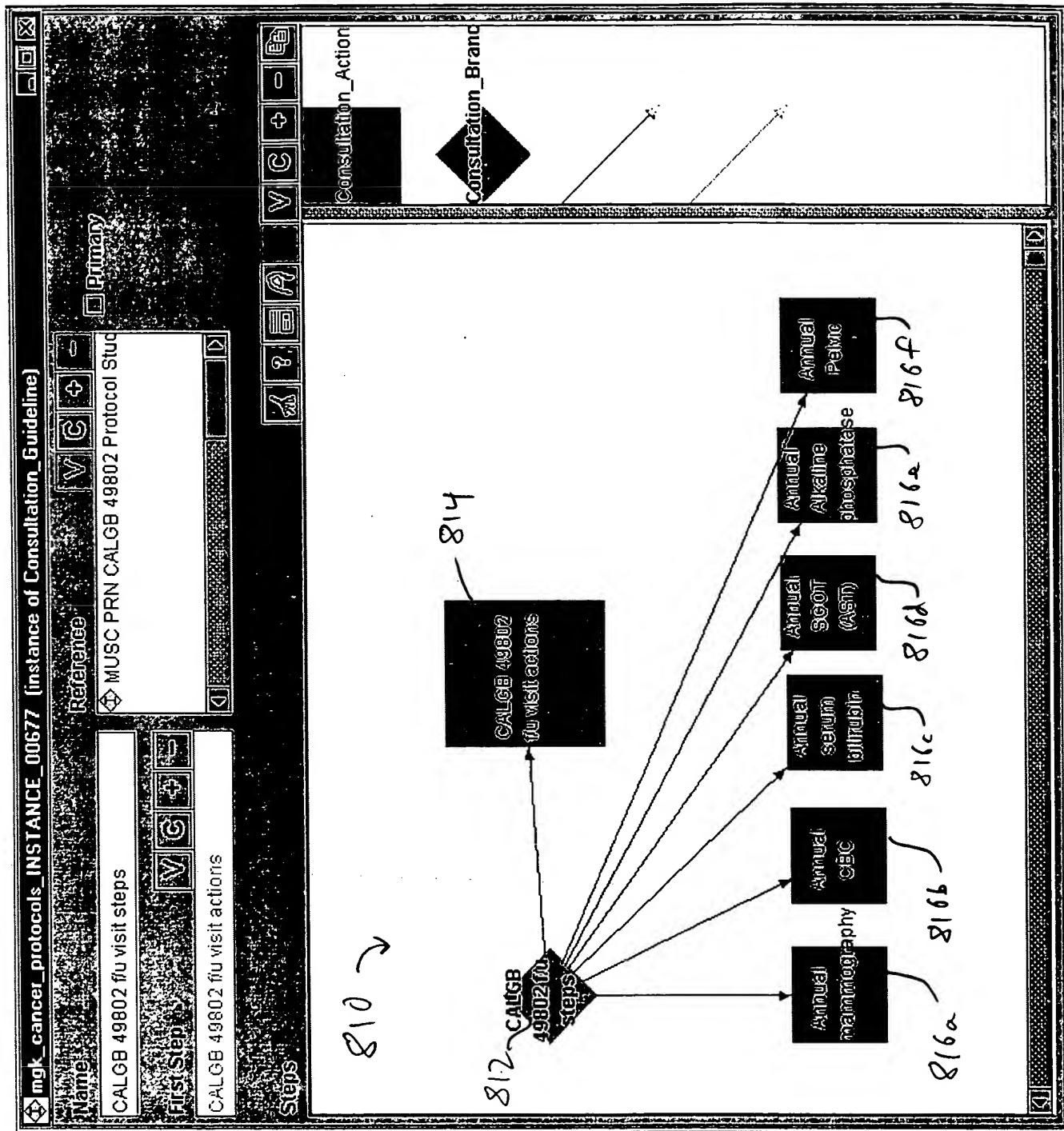


Fig. 8

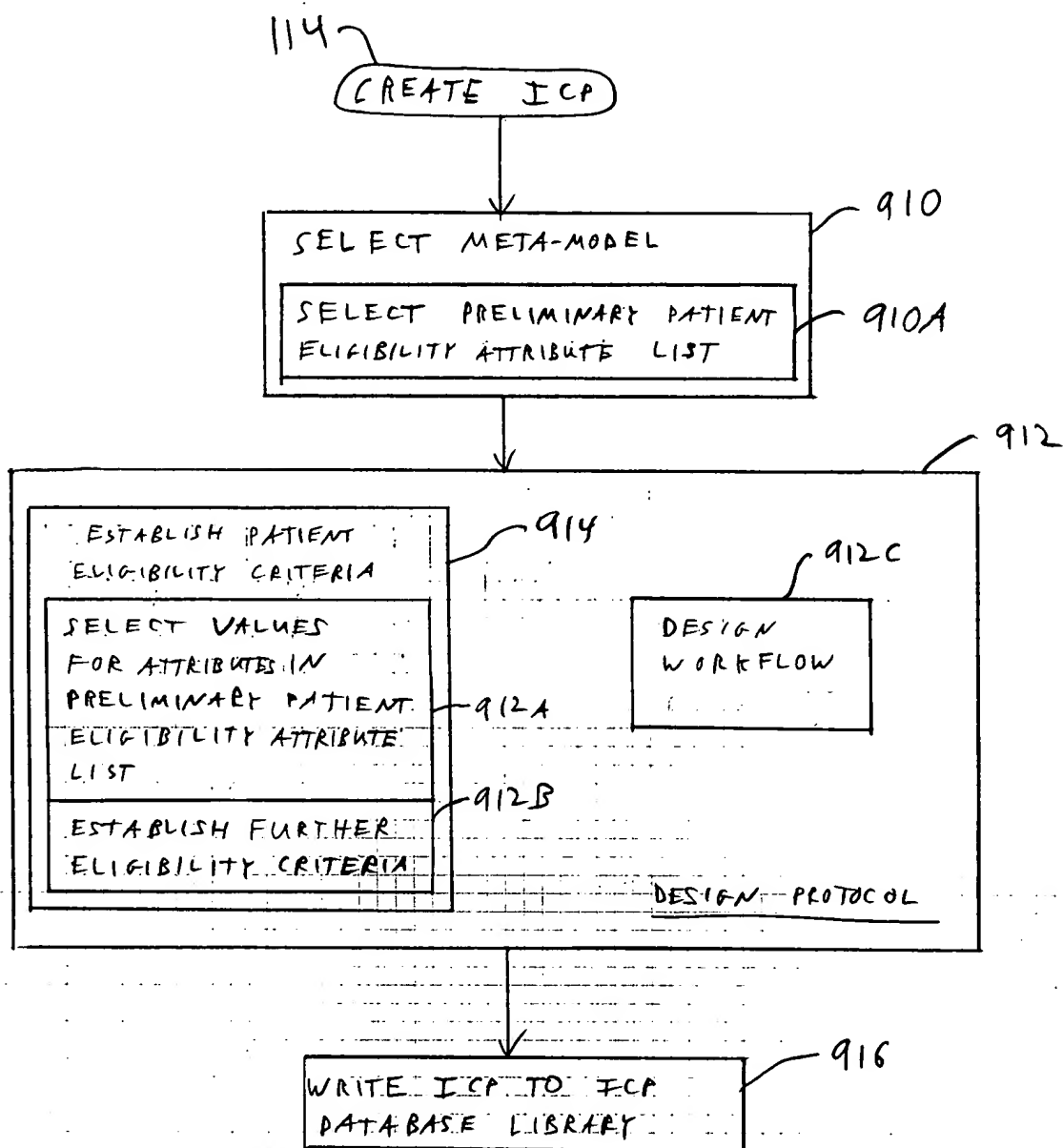


Fig. 1

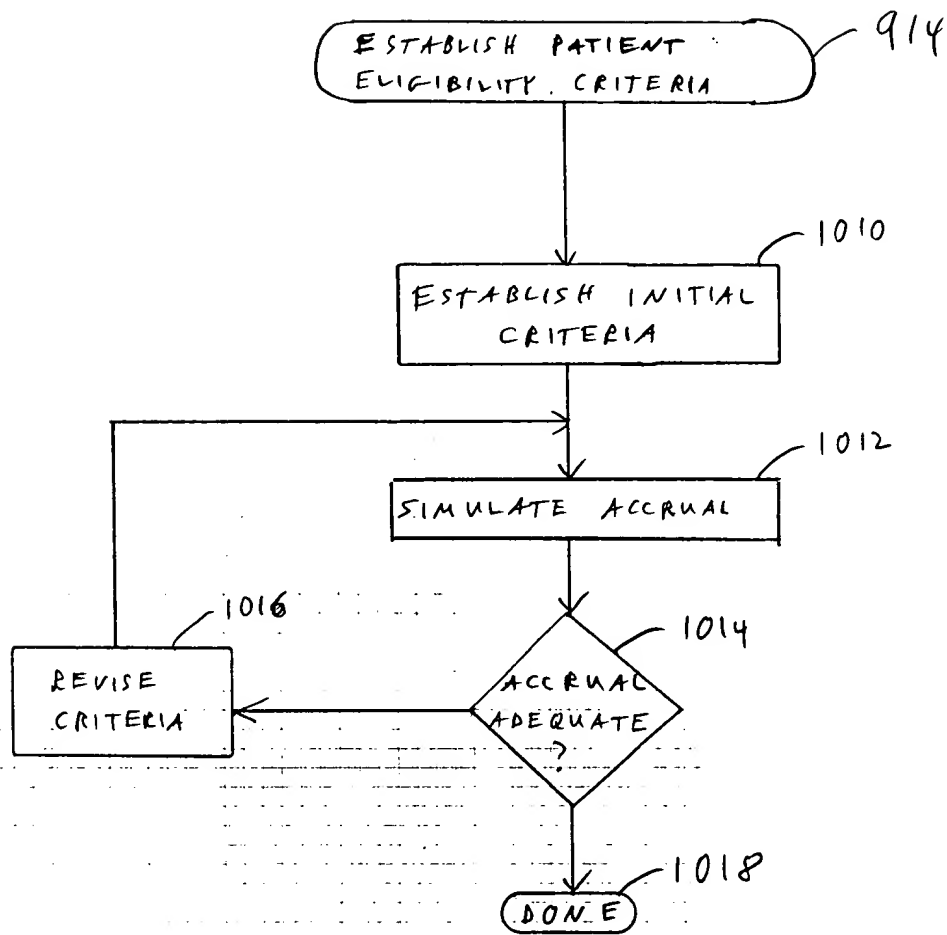


Fig. 10

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes Subclass V C X

Relationship: Subclass V C X

@THING A
 @CLASS A
 @SLOT A
 @FACET A
 @RDF Helper A
 @rdfs:Resource
 @RDF Data Type A
 @rdf:Property M
 @rdfs:Class M
 @Diagram_Entity
 @FastTrackClass
 @EligibilityCriteriaSet
 @ManagementTask - 1130
 @Transition A M
 @ProtocolSchemaDiagram M
 @Visit - 1128
 @EligibilityCriteria - 1126
 @Protocol:

1110

1112

1124

1116

1118

1114

Documentation

The document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol also usually gives the background and

Constraints

Name

Protocol

Role

Concrete

Template Slots

Other Facets

classes=(ProtocolSchemaDiagram)

1122

values=(Phase II,Phase IV,Phase I,Phase III)

values=(On hold, Terminated, Active)

1134

1120

protocolTitle

quickScreenCriterion

rdfs:isDefinedBy

rdfs:seeAlso

resource uri

shortDescription

siteAccrualTarget

siteLongDescription

siteShortDescription

sponsor

sponsorAccrualTarget

studyChair

trialPhase

trialStatus

1110

1114

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Fig. 11

001650 8016500

FastTrack Protocol_INSTANCE_00212 [instance of Protocol]	
ProtocolTitle	Version
A Phase III Study of Paclitaxel via Weekly 1-Hour Infusion v	Update #1
ProtocolIdentifier	VersionDate
CALGB 9840	December 15, 1998
OfficialSourceDocument	EligibilityCriteriaSet
http://prn.musc.edu/research/protocol/deptmed/divhnc/bri	CALGB 9840 Eligibility Criteria 1212
ShortDescription	LongDescription
CALGB 9840	
StudyChair	
Andrew D. Seidman, M.D.	
Sponsor	
CALGB	
QuickScreenCriterion	
Breast Cancer	
ProtocolObjectives	
To compare "standard" (S) paclitaxel at 175 mg/m ² via 3-hour infusion every 3 weeks to "dose-dense" (DD) paclitaxel at 80 mg/m ² via 1-hour infusion every week	
TrialStatus	FirstVisit
Active	Screening Visit
AccrualStatus	
Open for accrual	
TrialPhase	ProtocolSchemaDiagram
Phase III	CALGB 9840 Schema 1214
TrialType	
Cooperative group	

Fig. 12

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes Instances

Relationship: Subclass

THING A

CLASS A

SLOT A

FACET A

RDF Helper A

rdfs:Resource

RDF Data Type A

rdf:Property M

rdfs:Class M

Diagram_Entity

FastTrackClass

EligibilityCriteriaSet

ManagementTask

Transition A M

ProtocolSchemaDiagram M

Visit

EligibilityCriterion

Protocol

Superclasses

FastTrackClass

EligibilityCriteriaSet (Instance of rdfs:Class)

Name

EligibilityCriteriaSet

Role

Concrete

Constraints

Documentation

A criterion which determines whether or not a subject is eligible to participate in the study. A criterion is either an inclusion criterion that prospective subjects must meet to be eligible, or an

Template Slots

Name	Type	Cardinality	Default	Other Facets
exclusionCriteria	Instance	Multiple		classes={EligibilityCriterion}
inclusionCriteria	Instance	Multiple		classes={EligibilityCriterion}
longDescription	String	Single		
isDefinedBy	Instance	Single		classes={URI,rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI,rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy

Rdfs:seeAlso

Resource Uri

Fig. 13

1310

001650 " 92013560

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Relationship: Subclass V C X

Classes: **FastTrack** Instances

- THING A
- CLASS A
- SLOT A
- FACET A
- RDF Helper A
- rdfs:Resource
- ⊙ RDF Data Type A
- ⊙ rdt:Property M
- ⊙ rdfs:Class M
- Diagram Entity
- FastTrackClass
- ⊙ EligibilityCriteriaSet
- ⊙ ManagementTask
- ⊙ Transition A M
- ⊙ ProtocolSchemaDiagram M
- ⊙ Visit
- ⊙ EligibilityCriterion
- Protocol

Superclasses: +

- FastTrackClass

EligibilityCriterion (Instance of rdfs:Class)

Name: EligibilityCriterion

Role: Concrete

Constraints: V C + -

Documentation: A criterion which determines whether or not a subject is eligible to participate in the study. A criterion is either an inclusion criterion that prospective subjects must meet to be eligible, or an

Template Slots: V C + -

Name	Type	Cardinality	Default	Other Facets
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes={URI rdfs:Resource}
rdfs:seeAlso	Instance	Single		classes={URI rdfs:Resource}
resource uri	Instance	Single		classes={URI}
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

rdfs:isDefinedBy: V C + -

rdfs:seeAlso: V C + -

Resource Uri: V C + -

Fig. 14

1410

001650 92010500

FastTrack Protocol_INSTANCE_00074 (instance of EligibilityCriteriaSet)	
ShortDescription	LongDescription
CALGB 9840 Eligibility Criteria	
InclusionCriteria	
<input checked="" type="checkbox"/> Female	
<input checked="" type="checkbox"/> Breast adenocarcinoma that is inoperable, recurrent, or metastatic	
<input checked="" type="checkbox"/> More than 4 weeks since last chemotherapy	
<input checked="" type="checkbox"/> More than 6 weeks since treatment with nitrosureas, melphalan, or	
<input checked="" type="checkbox"/> More than 4 weeks since last hormonal therapy OR tumor measur	
<input checked="" type="checkbox"/> Age ≥ 18	
<input checked="" type="checkbox"/> Measurable disease	
<input checked="" type="checkbox"/> Granulocytes $\geq 1,500 / \text{ul}$	
<input checked="" type="checkbox"/> Platelet count $\geq 100,000 / \text{ul}$	
<input checked="" type="checkbox"/> Creatinine $\leq 2.0 \text{ mg/dl}$	
<input checked="" type="checkbox"/> Bilirubin within institutional normal limits	
<input checked="" type="checkbox"/> SGOT (AST) $\leq 3 \times$ upper limits of normal	
<input checked="" type="checkbox"/> Greater than 2 weeks from prior surgery	
ExclusionCriteria	
<input checked="" type="checkbox"/> More than 1 prior chemotherapy regimens for metastatic or locally	
<input checked="" type="checkbox"/> CNS metastases if untreated or symptomatic	1510
<input checked="" type="checkbox"/> Prior taxane for metastatic or locally-advanced breast cancer	
<input checked="" type="checkbox"/> Prior taxane in adjuvant setting where patient remained disease fr	
<input checked="" type="checkbox"/> Leptomeningeal carcinoma	
SiteLongDescription	
SiteShortDescription	
RefIsDefinedBy	
RefIsSeeAlso	
Resource Uri	

Fig. 15

FastTrack Protocol_INSTANCE_00073 (instance of EligibilityCriterion)	
ShortDescription	CNS metastases if untreated or symptomatic
LongDescription	Patients with central nervous system metastases are eligible only if the patient has completed cranial irradiation at least 6 months prior, is currently asymptomatic, and is not currently receiving corticosteroids for this condition.
SiteLongDescription	
SiteShortDescription	

1610 →

1612 →

Fig. 16

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes

Relationship: Subclass

THING A

CLASS A

SLOT A

FACET A

RDF Helper A

rdfs:Resource

RDF Data Type A

rdf:Property M

rdfs:Class M

Diagram_Entity

FastTrackClass

EligibilityCriteriaSet

ManagementTask

Transition A M

ProtocolSchemaDiagram M

Visit

EligibilityCriterion

Protocol

Instances

FastTrackClass

Visit (Instance of rdfs:Class)

Name

Visit

Constraints

V C + -

Role

Concrete

Documentation

An actual encounter between the provider and a patient on study. A number of possible visits are associated with a study (Protocol).

V C + -

Template Slots

Name	Type	Cardinality	Default	Other Facets
dataManagementTasks	Instance	Multiple		classes=(ManagementTask)
longDescription	String	Single		
patientManagementTasks	Instance	Multiple		classes=(ManagementTask)
possibleVisitTransitions	Instance	Multiple		classes=(VisitToVisitTransition)
rdfs:isDefinedBy	Instance	Single		classes=(URI,rdfs:Resource)
rdfs:seeAlso	Instance	Single		classes=(URI,rdfs:Resource)
resource uri	Instance	Single		classes=(URI)
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy

V C + -

Rdfs:seeAlso

V C + -

Resource Uri

V C + -

Fig. 17

1710

FastTrack Protocol_INSTANCE_00014 [instance of Visit]	
ShortDescription <div>Arm A Treatment Visit</div>	<div>1818</div> PossibleVisitTransitions <div> <input type="checkbox"/> Arm A Treatment to Arm A Treatment Retry #1 <input type="checkbox"/> Arm A Treatment to Long Term Followup <input type="checkbox"/> Arm A Treatment Visit to Arm A Treatment Visit </div>
<div>1814</div> DataManagementTasks <div> <input type="checkbox"/> Submit Form C-116 <input type="checkbox"/> Submit Form C-118 <input type="checkbox"/> Submit Form C-080 <input type="checkbox"/> Submit Form C-344 + Form C-080 (*) <input type="checkbox"/> Submit Form C-344 + Form C-272 (*) <input type="checkbox"/> Submit Form C-113 (*) <input type="checkbox"/> Submit Form C-260 (*) <input type="checkbox"/> Submit Form C-300 (*) </div>	<div>1810</div> PatientManagementTasks <div> <input type="checkbox"/> Confirm granulocytes $\geq 1500/\mu l$ <input type="checkbox"/> Confirm no G-CSF given in past 24 hours <input type="checkbox"/> Give Dexamethosone 10 mg IV, 30 minutes <input type="checkbox"/> Give Diphenhydramine 50 mg IV, 30 minutes <input type="checkbox"/> Give Cimetidine 300 mg IV, 30 minutes <input type="checkbox"/> Give anti-emetics (*) <input type="checkbox"/> Give Arm A Pacitaxel treatment — 1816 <input type="checkbox"/> Give G-CSF (*) <input type="checkbox"/> Evaluate Patient Response <input type="checkbox"/> Schedule next visit </div>
LongDescription <div>Arm A of the CALG 9840 consists of treatment with Pacitaxel 175 mg/m² administered as a 3 hour infusion intravenously every three weeks. One cycle is equivalent to one infusion. Treatment cycles will be repeated every 21 days as long as the patient has stable or responding disease. Granulocyte count must be $\geq 1500/\mu l$ and platelet count must be $\geq 100,000/\mu l$ on day 1 of each cycle. Patients should receive a minimum of two cycles of therapy, unless there is rapid disease progression ($>50\%$ increase in product of bi-dimensional measurements).</div>	
SiteLongDescription <div></div>	
SiteShortDescription <div></div>	

Fig. 18

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes Forms Instances

Relationship: Subclass

@THING A
 @CLASS A
 @SLOT A
 @FACET A
 @RDF Helper A
 @rdfs:Resource
 @RDF Data Type A
 @rdf:Property M
 @rdfs:Class M
 @Diagram_Entity
 @FastTrackClass
 @EligibilityCriteriaSet
 @ManagementTask
 @Transition A M
 @ProtocolSchemaDiagram M
 @Visit
 @EligibilityCriterion
 @Protocol

ManagementTask (Instance of rdfs:Class)

Name: ManagementTask

Role: Concrete

Documentation: A task related to this visit. Includes: checks that tasks prior to this visit occurred, oks that tasks performed during this visit were done, or reminders for tasks to perform before

Constraints: [V] [C] []

Template Slots

Name	Type	Cardinality	Default	Other Facets
longDescription	Symbol	Single		values=(Medium,High,Low)
longDescription	String	Single		
rdfs:isDefinedBy	Instance	Single		classes=(URI,rdfs:Resource)
rdfs:seeAlso	Instance	Single		classes=(URI,rdfs:Resource)
resource uri	Instance	Single		classes=(URI)
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

Rdfs:isDefinedBy [V] [C] []

Rdfs:seeAlso [V] [C] []

Resource Uri [V] [C] []

Superclasses: []

@FastTrackClass

Fig. 19

FastTrack Protocol_INSTANCE_00206 (Instance of ManagementTask)	
ShortDescription	
Give Arm A Paclitaxel treatment	
LongDescription	
<p>Give Paclitaxel 175 mg/m² IV, 3 hours. This treatment is given to patients in Arm A of the CALGB 9840 protocol. It is given once every 3 weeks. One cycle is equivalent to one infusion. Granulocyte count must be $\geq 1500/\mu\text{l}$ and platelet count must be $\geq 100,000/\mu\text{l}$ on day 1 of each cycle in order to proceed with the Paclitaxel infusion. Patients must receive the pre-medication prior to Paclitaxel infusion. If either the granulocyte or platelet count are not adequate, do not continue with treatment. Patients should receive a minimum of 2 cycles unless there is rapid disease progression.</p> <p>Expected toxicities:</p> <p>The dose-limiting toxicity of Paclitaxel is neutropenia. Other known toxicities include nausea and vomiting, diarrhea, stomatitis, mucositis, pharyngitis, typhilitis, ischemic colitis, bradycardia, atrial arrhythmia, hypotension, sensory (taste), peripheral neuropathy, seizures, mood, hepatic encephalopathy, acute anaphylactoid and urticarial reactions, flushing, rash, pruritis, increased SGOT, SGPT, bilirubin and/or alkaline phosphatase, hepatic failure, hepatic necrosis, alopecia, fatigue, arthralgia, myalgia, light-headedness, myopathy, visual changes (sensation of flashing lights, blurred vision). Local infiltration with Paclitaxel will cause mild local symptoms (erythema, discomfort, induration) that usually resolve within a week. If infiltration occurs, there is the rare possibility of ulceration or rash. Seizure have been reported rarely in association with Paclitaxel use.</p> <p>Dose Modifications:</p> <p>Allergic Reactions: Patients with grade 1 or 2 allergic reactions may have treatment continued without modifications. Patients with grade 3 or 4 allergic reactions who are responding to treatment may remain on protocol therapy after discussion with Study Chair. Such patients are at risk for recurrent allergic reactions. As a first maneuver, retreatment after premedication with oral recurrent allergic reactions. As a first maneuver, retreatment after premedication with oral dexamethasone 20 mg at 12 and 6 hours pre-administration of Paclitaxel, along with IV H1 and H2-receptor antagonist should be attempted. If necessary, thereafter, infusion rate adjustments will be considered and additional premedications will be administered. These patients must be informed of the potential risks of recurrent allergic reactions and must be carefully monitored.</p> <p>Hematologic Toxicity: Patients are to be managed as clinically indicated. Colony stimulation factors (G-CSF) should be used in the manner described below. Exceptions should be discussed with the Study Chair.</p> <p>Site/LongDescription</p>	

Fig. 20

001650 96010500

FastTrack Protocol_INSTANCE_00196 (instance of ManagementTask)	
ShortDescription	
Submit Form C-116	
LongDescription	Submit CALGB Advanced Breast Cancer Followup-form (C-116) every two cycles while on protocol therapy, at 6 & 12 months after end of treatment, at disease progression or initiation of non-protocol therapy.
SiteLongDescription	
SiteShortDescription	

Fig. 21

FastTrack Protocol Protégé-2000 [C:\My Documents\Latest FastTrack RDF + CALGB 9840\FastTrack Protocol.ppt]

Project Edit Window Help

Classes

Relationship: Subclass

Thing A

CLASS A

SLOT A

FACET A

RDF Helper A

rdfs:Resource

RDF Data Type A

rdf:Property M

rdfs:Class M

Diagram_Entity

FastTrackClass

EligibilityCriteriaSet

ManagementTask

Transition A M

VisitToVisitTransition M

ProtocolSchemaDiagram M

Visit

EligibilityCriterion

Protocol

Instances

2210

VisitToVisitTransition

ProtocolSchemaDiagram

Visit

EligibilityCriterion

Protocol

VisitToVisitTransition (Instance of Connector Metaclass)

Name

VisitToVisitTransition

Constraints

Documentation

A one-way link between a source visit (first_object) and a target visit (second_object). The inherited descriptions specify guidance about when/how/why to make this transition.

Role

Concrete

Template Slots

Name	Type	Cardinality	Default	Other Facets
first_object	Instance	Single		classes={URI,rdfs:Resource}
longDescription	String	Single		classes={URI,rdfs:Resource}
maximumRelativeTime	String	Single	-2218	classes={URI}
minimumRelativeTime	String	Single	-2220	classes={URI}
preferredRelativeTime	String	Single	-2222	classes={URI}
rdfs:isDefinedBy	Instance	Single		classes={URI}
rdfs:seeAlso	Instance	Single		
resource uri	Instance	Single		
second_object	Instance	Single	-2216	
shortDescription	String	Single		
siteLongDescription	String	Single		
siteShortDescription	String	Single		

First Object Slot Pointer

Second Object Slot Pointer

Rdfs:isDefinedBy

Rdfs:seeAlso

Fig. 22

2212

FastTrack Protocol_INSTANCE_00023 (instance of VisitToVisitTransition)

ShortDescription

Arm A Treatment to Arm A Treatment Retry #

FirstObject

Arm A Treatment Visit

SecondObject

Arm A Treatment Retry #1

V

C

+

-

V

C

+

-

PreferredRelativeTime

7

MaximumRelativeTime

7

MinimumRelativeTime

7

LongDescription

If either granulocyte or platelet count are not adequate, blood counts should be repeated weekly and treatment should be instituted when there has been hematologic recovery. Patients receiving G-CSF are not eligible for re-treatment unless they have been off G-CSF for a minimum of 24 hours.

SiteLongDescription

SiteShortDescription

Fig. 23

FastTrack Protocol Protégé-2000 (C:\My Documents\Latest FastTrack RDF + CALGB 9840V\FastTrack Protocol.ppt)

Project Edit Window Help

Classes

Relationship: Subclass

Thing A

CLASS A

SLOT A

FACET A

RDF Helper A

rdfs:Resource

RDF Data Type A

rdf:Property M

rdfs:Class M

Diagram_Entity

FastTrackClass

EligibilityCriteriaSet

ManagementTask

Transition A M

VisitToVisitTransition

ProtocolSchemaDiagram M

Visit

EligibilityCriterion

Protocol

Superclasses

FastTrackClass

Network A

ProtocolSchemaDiagram (Instance of Network_Metaclass)

Name

ProtocolSchemaDiagram

Role

Concrete

Constraints

Documentation

The ProtocolSchemaDiagram is the part of the protocol which details the design of the trial. A protocol schema's first visit is always at least one screening visit, which is assumed

Template Slots

Name

Type

Cardinality

Default

Other Facets

connectors

Instance

Multiple

classes=(VisitToVisitTransition)

diagramNodes

Instance

Multiple

classes=(Visit)

last_divider_location

Integer

Single

2412

classes=(ObjectLocation)

layout_information

String

Single

longDescription

Integer

Single

main_panel_height

Integer

Single

main_panel_width

Integer

Single

rdfs:isDefinedBy

Instance

Single

classes=(URI,rdfs:Resource)

rdfs:seeAlso

Instance

Single

classes=(URI,rdfs:Resource)

resource uri

Instance

Single

classes=(URI)

shortDescription

String

Single

siteLongDescription

String

Single

siteShortDescription

String

Single

Node Slot

diagramNodes

V C + -

Rdfs:isDefinedBy

V C + -

Rdfs:seeAlso

V C + -

Fig-24

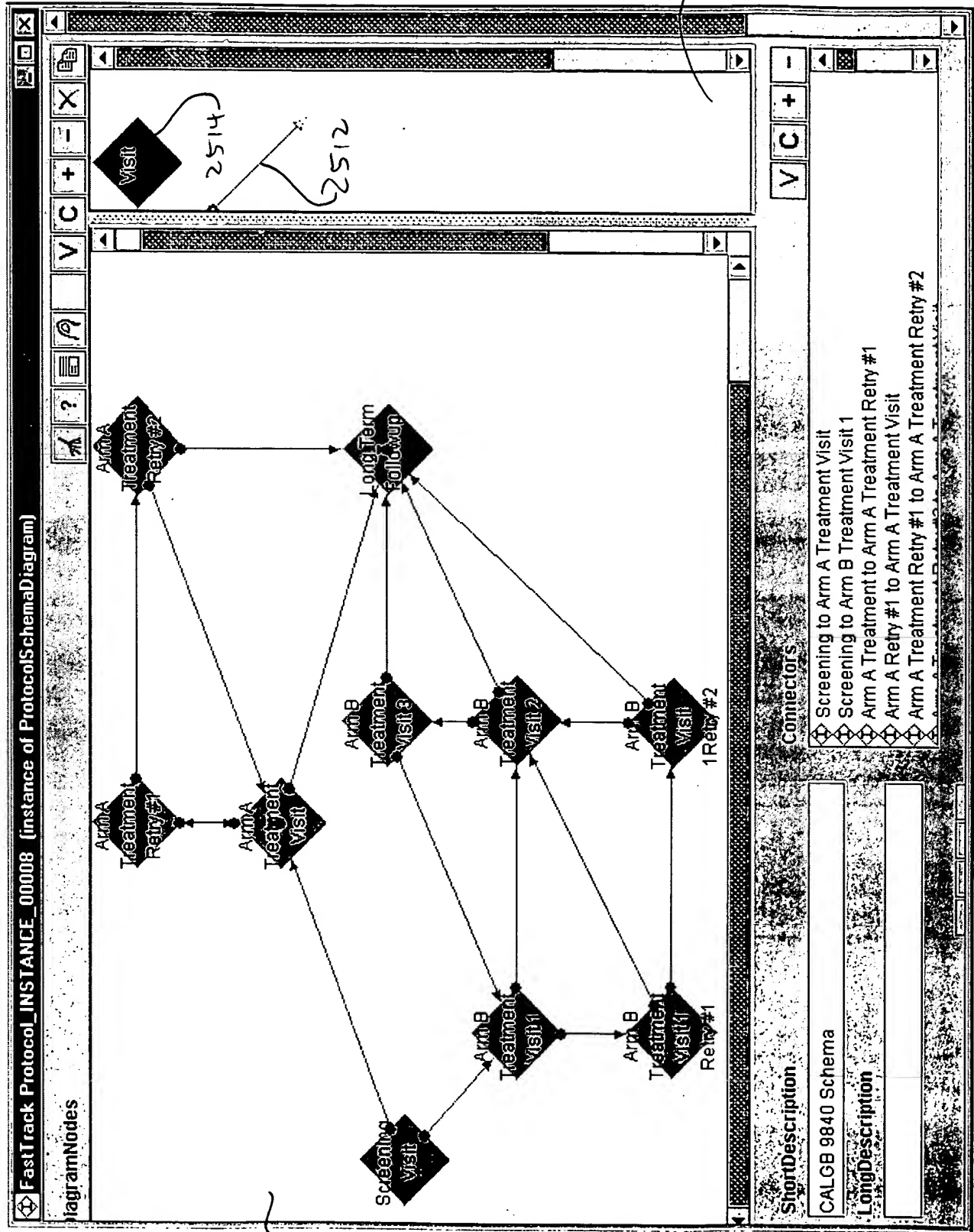


Fig. 25

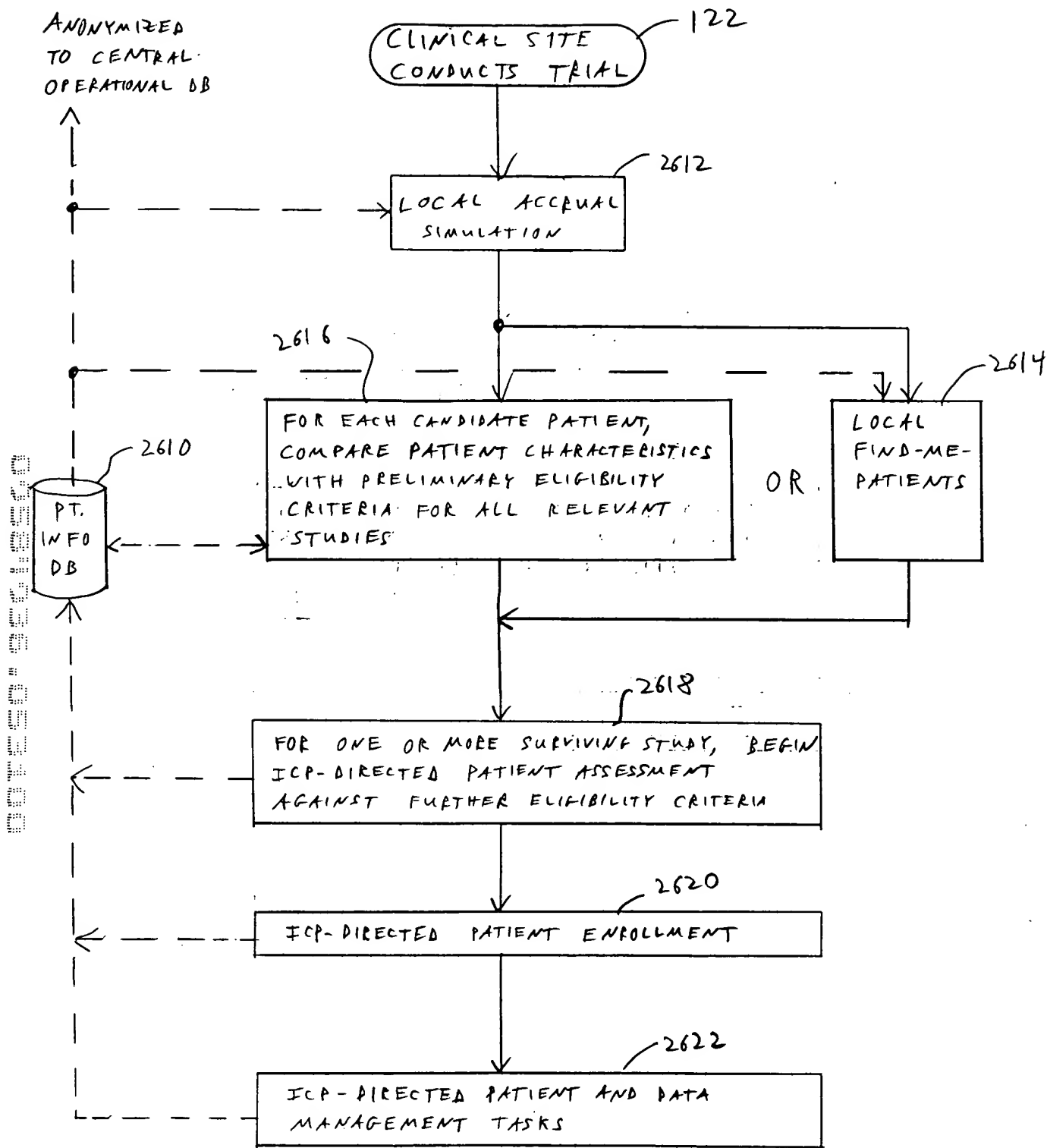


Fig. 26